

- - REMARKS - -

Claims 1-14, 16-24, 26-68, 70-78, and 80-107 are currently pending in the application. Claims 13-14, 17, 22-24, 30-52, 64-68, 71, 76-78, and 84-107 have been withdrawn from consideration. Claims 1 and 53 have been amended. The changes to the amended claims from the previous versions to the rewritten versions are shown above with strikethroughs for deleted matter and underlines for added matter. No new matter has been added as a result of these amendments.

In the outstanding final Office Action, claims 1-12, 16, 18-21, 26-29, 53-63, 70, 72-75, and 80-83 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner has asserted that the specification does not appear to support that the needle comprises a flexible shaft, as called for by independent claims 1 and 53. Applicants respectfully disagree. Figs. 1, 5, 7, 8, 12, 14, and 14A-C illustrate various embodiments of the present invention and show a needle 26, 126 extending through a sheath 22, 122. It is apparent from each of these drawings that both the sheath and the needle are sufficiently flexible to form a 180° bend therein. Moreover, Fig. 15 and the description thereof (set forth on page 22 of the specification) describes an exemplary method of using the apparatus of the present invention to obtain a cytology sample from a mammalian body by inserting an endoscope into the mammalian body and then inserting apparatus through the working lumen of the endoscope. It is well understood by those of ordinary skill in the art that endoscopes must have sufficient flexibility to allow advancement through various bodily lumens, many of which follow a curvilinear pathway. As a consequence, the apparatus of the present invention must likewise be sufficiently flexible to pass through the working channel of the endoscope.

In the outstanding final Office Action, claims 1-2, 7, 9-11, 20, and 29 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 7,056,293 to Reeves et al. (hereinafter "Reeves"). Claims 3-6, 8, 12, 16, 18-19, 21, 26-28, 53-63, 70, 72-75, and 80-83 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Reeves in view of U.S. Patent No. 4,966,162 to Wang (hereinafter "Wang"), U.S. Patent No. 6,579,279 to Rabiner et al. (hereinafter "Rabiner"), U.S. Patent No.

7,108,661 to Secrest et al. (hereinafter "Secrest"), and/or U.S. Patent No. 6,108,439 to Ishiguro (hereinafter "Ishiguro"). The rejections under 35 U.S.C. §§ 102(b) and 103(a) are respectfully traversed.

Independent claim 1 is directed to an apparatus for collecting a cytology sample, wherein the apparatus comprises a needle, a stylet and a cytology collection device. Both the needle and the cytology collection device are adapted to extend through the lumen of the needle, although not at the same time. The needle comprises an elongate flexible shaft that is adapted to extend through the working channel of an endoscope. Thus, the apparatus is specifically adapted to collect a cytology sample from a remote location with the patient. Independent claim 53 is directed to a method of collecting a cytology sample by providing an apparatus having these same limitations. The apparatus and method are neither disclosed nor suggested by the prior art.

Reeves is directed to an apparatus for diagnosing and/or sampling ovarian tissue. Although Reeves discloses an introducer needle (10) through which other devices may be inserted, it is clear that the introducer needle is not adapted to extend through an endoscope. To the contrary, the introducer needle is adapted to permit a fiber optic device to be extended therethrough. Thus, Reeves teaches away from the needle of the present invention, which must be adapted to extend through the working channel of an endoscope. Moreover, it is apparent that the introducer needle of Reeves does not comprise a flexible shaft, as further required by claims 1 and 53 of the present invention. This is not surprising since the Reeves introducer needle is not adapted to extend through the working channel of an endoscope. This is further evidence that Reeves is not relevant to present invention. The other references likewise fail to disclose or suggest these same limitations.

In paragraph 35 of the final Office Action, the Examiner repeats the assertion that the specification does not provide any support for the limitation of claims 1 and 53 requiring that the needle comprise an elongate flexible shaft. Applicants respectfully disagree with the assertion for at the least the reasons set forth above in connection with its traversal of the rejections under 35 U.S.C. § 112, first paragraph.

The Examiner also asserts since the Reeves needle is presumably made of the same materials as the needle of the present invention, then the Reeves needle would

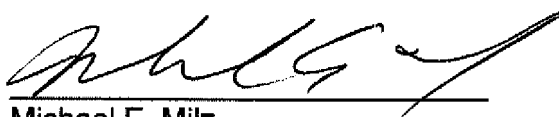
provide the same manner of flexibility. Applicants respectfully disagree. As explained above, the needle of the present invention must be sufficiently flexible to pass through a endoscope, which in turn must be sufficiently flexible to pass through the typical curvilinear bodily lumens of a mammal. Moreover, drawings for the instant application illustrate an example of the degree of flexibility of that a needle of the present invention may posses. There is no suggestion that the Reeves needle has any flexibility at all, let alone a sufficient flexibility to pass through and endoscope.

In paragraph 36 of the final Office Action, the Examiner asserts that the current recitation of the needle being adapted to extend through an endoscope does not constitute a positive claim recitation. Applicants respectfully disagree. Claims 1 and 53 have nevertheless been amended to clarify the matter.

In view of the above, independent claims 1 and 53 are not rendered unpatentable in view of the prior art. The remaining non-withdrawn claims are dependent on either claim 1 or 53. Thus, these remaining non-withdrawn claims are likewise not rendered unpatentable in view of the prior art.

It is therefore believed that the application is in condition for allowance, and such allowance is now earnestly requested. If for any reason the Examiner is not able to allow the application, he is requested to contact the Applicants' undersigned attorney at (312) 321-4273.

Respectfully submitted,



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